PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2004 ST 106 E	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IT2004/000536	International filing date *(day/month/year)* 29.09.2004	Priority date *(day/month/year)* 29.09.2004
International Patent Classification (IPC) or national classification and IPC INV. A01N1/02 B65G1/137 A61M1/36		
Applicant ANGELANTONI INDUSTRIE SPA et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.07.2006	28.12.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer BICHLMAYER, K Telephone No. +49 89 2399-2977

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IT2004/000536

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

3-10	as originally filed
1, 2	received on 19.07.2006 with letter of 17.07.2006

Claims, Numbers

1-31	received on 19.07.2006 with letter of 17.07.2006

Drawings, Sheets

1/3-3/3	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-31
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-31
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-31
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 : IT UD 960 073 A1 (ANGELANTONI INDUSTRIE SPA) 10 November 1997 (1997-11-10)

D2 : US 5 520 450 A (COLSON, JR. ET AL) 28 May 1996 (1996-05-28)

The document D1 is regarded as being the closest prior art to the subject-matter of claims 1 and 13, and shows (cf. abstract and pages 5 to 9; the references in parentheses applying to this document) a method for receiving, preserving and releasing blood bags in a temperature and closure controlled apparatus (22) provided with at least one interface (13, 15) for interacting with an user, comprising the steps of providing blood bags (18) with coded identification means (28) which also comprise data concerning the blood contained in the same bag, before receiving in said apparatus (22) or drawing therefrom a bag (18), obtaining from said coded-identification means (28) the data concerning the blood contained in the bag and storing them in a memory (cf. page 7, lines 5 to 6).

The subject-matter of claim 1 differs from this known D1 in that data concerning the blood contained in the bag are exchanged with a data management system external to said apparatus.

Moreover, D1 discloses (cf. Figs. 1 and 3 and the related description) an apparatus for preforming the method according to claim 1 from which the subject-matter of claim 13 differs in that an external data-management is provided with which the apparatus can interact and which is capable to exchange data from and to data-processing system for checking the receiving, preservation and releasing of the bags.

The subject-matter of independent claims 1 and 13 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as providing a method step and an apparatus option enabling centralized administration of the bags and their

content.

The solution to this problem proposed in claims 1 and 13 of the present application is considered as involving an inventive step (Article 33(3) PCT) as none of the available prior art documents discloses said data exchange step or said external data management system.

Claims 2 to 12 and 14 to 31 are dependent on claims 1 and 13, respectively, and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Apparatus and method for receiving, storing and distributing blood bags.

* * *

DESCRIPTION

The present invention refers to an automated and computerised apparatus and to a method for receiving, preserving and releasing blood bags.

The company Angelatoni developed an apparatus of this type: this consisted substantially of a refrigerator inside which there is a rotating magazine equipped with cells for containing blood bags blood; the refrigerator is locally controlled by a local electronic computer (so called Personal Computer or PC) by way of a series of electrical connections. An electrical connection is provided for each sensor and an electrical connection for each actuator; all the electrical connections are grouped in two large multi-wire cables.

The approach followed in the designing of that apparatus is the conventional one, which is used when a computerised machine-tool is designed: that is to say, the mechanics are separated from the electronics and the sensors and actuators are placed at the interface. Such an approach could be very sensible; in fact, the mechanics and the electronics have little in common; in general there is no advantage in placing them close to one another (on the contrary, it may be difficult), and it is quite often necessary to keep them distant from each other. The PC is of conventional type and therefore it is very easy to load software of commercial type as well as the developed one.

Recently, Angelantoni decided to carry out some research activity in order to improve both the older version of the apparatus (1) and software thereof. Therefore a suitable control program was developed and loaded onto a data processing system (which can be advantageously a PC) of the apparatus.

As a result of this activity, it was realised that such an apparatus for blood bags is very different from a computerised machine tool.

Firstly, its principal activity (that is to say, preserving the blood bags at the correct temperature) is carried out in the absence of an operator.

This activity is very important and therefore safety and reliability of the apparatus are key factors.

The apparatus is typically placed in locations with free access, so there is the need for the access to the blood bags to be carefully controlled. Also, every operation regarding movements of the bags should be tracked and saved as a "history" document.

Since possible malfunctions and errors of such an apparatus (in the receiving and/or preservation and/or release of the blood bags) may have very serious consequences regarding the life not only of one but also of several human beings, such apparatus must be

(1), AS DISCLOSED IN THE ITALIAN PATENT APPLICATION N. UD96A000073 TO ANGELANTONI INDUSTRIE SPA, PUBLISHED ON NOVEMBER, 10 1997,

very reliable and free from system crashes.

Also, such an apparatus should not be a closed system, but should be instead able to exchange data with the environment it is working in, in order to retrieve external information about the blood bags to be stored/drawn and to give information about the same bags upon a remote request.

(i) The present invention arises from these observations. The aim of the present invention is to provide an apparatus for receiving, preserving and releasing blood bags that is a stand-alone unit capable of fully managing its own functions and interacting with its external working environment to exchange key data.

This aim is substantially achieved by the apparatus having the characteristics disclosed in independent claim 1. Advantageous features of the present invention are disclosed in the dependent claims.

Another aim of the present invention is to provide a method for receiving, preserving and releasing blood bags that is capable of overcoming all the drawbacks of the prior realizations.

The ideas underlying the present invention are

- to enclose all the components of the apparatus, including the data-processing system, in a single cabinet, in order for the apparatus to be compact and safer;
- to provide the apparatus with a computerized control system which autonomously manages the functions of the apparatus;
- to provide the apparatus with data processing and logic means (advantageously by means of a control program) to exchange key data from and to an external data management system, with which the apparatus according to the invention can interact, and to store said data in a memory. In particular, said data concern the bag and the blood contained therein.

The method according to the invention is a method for receiving, preserving and releasing blood bags in a temperature and closure controlled apparatus provided with at least one interface to interact wit an user, comprising the steps of:

- providing the blood bags with coded-identification means which also comprise data concerning the blood contained in the same bag;
- before receiving in said apparatus or drawing therefrom a bag, obtaining from said coded-identification means the data concerning the blood contained in the bag and storing them in a memory.

The present invention will become clear from the following description to be considered in conjunction with the appended drawings, in which:

Figure 1 shows the simplified internal block diagram of an exemplary embodiment of an

A CLOSE SYSTEM THAT PUTS TOGETHER A COOLING SYSTEM AND A DATA PROCESSING SYSTEM, WHEREIN THE INTERFACE WITH THE USER IS PLACED AT A WALL OF THE CLOSE SYSTEM, IS DISCLOSED IN THE US PATENT APPLICATION N. 5 520 450 TO COLSON

CLAIMS

1. Method for receiving, preserving and releasing blood bags in a temperature and closure controlled apparatus (1) provided with at least an interface (8, 9) for interacting with an user, comprising the steps of:

- providing the blood bags with coded-identification means which also comprise data concerning the blood contained in the same bag;
- before receiving in said apparatus (1)or drawing therefrom a bag, obtaining from said coded-identification means the data concerning the blood contained in the bag and storing them in a memory

characterised in that it further comprises the step of

- exchanging the data concerning the blood contained in the bag with a data-management system (17) external to said apparatus (1).

2. Method according to claim 1; wherein the operations on said apparatus (1), in particular the drawing or the storing of bags, are subordinate to a procedure for acknowledgment of the operator through said interface (8, 9).

3. Method according to claim 2, wherein said procedure for acknowledgment involves the inserting of a key-word.

4. Method according to claim 3, wherein the data concerning the blood contained in the bag are cross-checked with corresponding data present in the external data-management system (17).

5. Method according to claim 4, further comprising for the drawing of a bag the steps of:

- providing an operator with a coded request for the bag to be drawn emitted on the basis of data contained in the external data-management system (17);
- performing a reading of the code of the request and cross-checking the validity of the request itself by asking an acknowledgment to the external data-management system (17);
- only after receiving an affirmative acknowledgment, calling for the reading of the coded-identification means and cross-checking with a code previously acquired from the request enabling the operator to conclude the drawing on the basis of the result of the cross-check.

6. Method according to any claim from 1 to 5, wherein the data concerning the blood contained in the bag are used to check the compatibility of the blood with a patient to whom the bag is going to be delivered by checking said data in the external data-management system (17).

7. Method according to any claim from 1 to 6, wherein the data concerning the blood contained in the bag are used to check the blood's expiry date.

8. Method according to any claim from 1 to 7, wherein the data concerning the blood contained in the bag

are used to arrange the bags inside said apparatus (1) in accordance with blood type, expiry date, destination and intended use of the blood.

9. Method according to any claim from 1 to 8, wherein the data concerning both particular blood type and the bags containing it are used to generate a signal of lack of bags and/or to identify a minimum supply of bags containing blood of said blood type.

10. Method according to claim 9, wherein the drawing of a bag whose blood type belongs to said minimum supply is denied.

11. Method according to any of the preceding claims, wherein two or more apparatuses (1) are linkable together in order to exchange data concerning the blood contained in the apparatuses (1).

12. Method according to claim 11, wherein from a remote apparatus (1) another apparatus (1) is remotely monitored and/or controlled and/or an operator thereof is guided.

13. An apparatus (1) for performing the method according the preceding claims, comprising:

- a cabinet (2) for containing all the components of the apparatus (1),
- a refrigerated space (21) for containing the bags,
- a magazine (3) comprising a plurality of cells (31), each capable of containing a single bag, the magazine (3) being housed inside the refrigerated space (21), each of the cells (31) being identified by a cell code,
- at least one door (4) for allowing access by an operator to the cells (31),
- a movement system (5) housed inside the cabinet (2) and capable of moving, preferably rotating, the cells (31),
- a cooling system (6) housed inside the cabinet (2) and capable of cooling the refrigerated space (21),
- a data-processing system (7) housed inside the cabinet (2), capable of controlling the movement system (5) and the cooling system (6), and capable of controlling the receiving, the preservation and the releasing of the bags,
- a keyboard (8) and a screen (9), both connected to the processing system (7), and both placed at a wall (23) of the cabinet (2),

characterised in that it further comprises

- an external data-management system (17), with which the apparatus (1) can interact, and capable to exchange data from and to data-processing system (7) for checking the receiving, preservation and releasing of the bags,

14. An apparatus (1) according to claim 13, capable of receiving, preserving and releasing blood bags equipped with bag identification means, comprising a reading device (10) for reading bag identification

means, said device (10) being connected to the processing system (7), housed inside the cabinet (2) and placed at a wall (23) of the cabinet (2).

15. An apparatus (1) according to claim 13 or claim 14, wherein the cells are structured in superposed levels, and wherein the cell code is univocal.

16. An apparatus (1) according to claim 15, wherein the cell code is independent of the level in which the cell is located and of the position of the cell in the level.

17. An apparatus (1) according to any of the preceding claims from 13 to 16, wherein cell identification means (31) capable of retrieving and/or containing cell codes, preferably bar codes, are placed at the cells.

18. An apparatus (1) according to claim 17, comprising at least one reading device (132) for reading cell identification means and connected to the processing system (7), and at least one corresponding movement member (131) for said reading device controlled by the processing system, said device and said member being housed inside the refrigerated space.

19. An apparatus (1) according to any claims from 13 to 18, wherein a service machinery space (22) separate from the refrigerated space (21) is provided and contains the movement system (5), the processing system (7) and the cooling system (6) of the refrigerated space (21) except for the evaporator (6A).

20. An apparatus (1) according to any of the claims from 13 to 19, comprising a metal container capable of completely containing the processing system.

21. An apparatus (1) according to any of the claims from 13 to 20, wherein the data-processing system (7) comprises a sub-system (7A) for thermal control of the refrigerated space (21), said sub-system being independent of, but in communication with, the processing system (7).

22. An apparatus (1) according to claim 21, wherein the sub-system (7A) is provided with an emergency power source.

23. An apparatus (1) according to any of the claims from 13 to 22, comprising a door which extends from the first to the last level of the magazine, wherein one cell of each level is notional, and wherein the movement system is capable of rotating a single level at a time.

24. An apparatus (1) according to any of the claims from 13 to 22, comprising a number of doors equal to the

number of levels of the magazine, wherein the movement system is capable of rotating the whole magazine, wherein the processing system is capable of releasing the opening of a single door at a time during normal operation.

25. An apparatus (1) according to any of the claims from 13 to 24, comprising a modem (12) of the wired or wire-free type for connecting the processing system (7) to a telephone network (13) or another apparatus (1).

26. An apparatus (1) according to any of the claims from 13 to 25, comprising a network port (11) of the wired or wire-free type for connecting the processing system (7) to a computer network (14) or another apparatus (1).

27. An apparatus (1) according to any of the claims from 13 to 26, wherein the data-processing system (7) comprises a control program (18) equipped with a communication module (19) capable of communicating with an external management program (17), typically by way of a network port (11) or a modem (12).

28. An apparatus (1) according to claim 27, wherein the communication module (19) is a software element independent of the control program (18) and is capable of being actuated by the control program (18) during the execution of the control program (18).

29. An apparatus (1) according to claim 27, wherein the control program (18) is equipped with a software interface (20) that is fixed and predetermined for interacting with the communication module (19).

30. Apparatus, according to any claim 13 to 29, including a computer program capable of performing all the steps of data management and control of the apparatus (1) in the claims from 1 to 12.

31. Computer program as claimed in claim 30, incorporated in a computer readable medium.